

FILED
ASHEVILLE, N.C.

APR 18 2017

U.S. DISTRICT COURT
W. DIST. OF N.C.

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Department of Veteran Affairs ("VA") (collectively the "United States"), Baxter International Inc., and Baxter Healthcare Corporation (collectively "Baxter"), and Warren Christopher Wall (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Baxter is a health care company with headquarters in Deerfield, Illinois. Baxter produces intravenous solutions used in the delivery of fluids and drugs to patients. Baxter has a production facility in Marion, North Carolina.

B. On February 15, 2013, Relator, Warren Christopher Wall ("Relator") filed a *qui tam* action in the United States District Court for the Western District of North Carolina captioned *United States ex rel. Christopher Wall v. Baxter International, Inc. and Baxter Healthcare Corporation* (Civil Action No. 1:13-cv-42), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). Relator filed an amended complaint on September 14, 2014. Relator then filed a Second Amended Complaint on January 28, 2015. Relator alleges that Baxter violated Current Good Manufacturing Practice ("CGMP") regulations in its production of various intravenous drug products, resulting in the sale of legally adulterated drugs in violation of the Food, Drug and Cosmetics Act ("FDCA").

C. The state plaintiffs (namely: California, Colorado, Connecticut, Georgia, Hawaii, Illinois, Iowa, Maryland, Massachusetts, New York, North Carolina, Virginia, and Washington) declined to intervene in this action.

D. The United States contends that it has certain civil claims against Baxter, as specified below, for engaging in the following conduct (hereinafter referred to as the "Covered Conduct"):

1. The United States alleges that, during the period January 1, 2011, through December 31, 2012, Baxter sold the following products to the VA under Contract Nos. V797P-9112, VA797P-12-C-0007, and VA797P-12-C-0033 (collectively "the VA Contracts"):

NDC	Product
1. 0338-0049-04	Sodium Chloride 0.9% Inj, Bag 1000ml
2. 0338-0085-04	Dextrose 5%/NACL 0.45% INJ
3. 0338-0089-04	Dextrose 5%/NACL 0.9% INJ
4. 0338-0117-04	Lactated Ringers INJ

2. The United States alleges that the products described in paragraph D.1 and sold to the VA under the VA Contracts were produced by Baxter in violation of CGMP regulations and, as such, the FDCA in contravention of the VA Contracts. The United States further alleges that, as a result, Baxter caused to be submitted false claims to the VA in violation of the FCA.

E. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs. The parties agree that nothing in this Paragraph or this Agreement shall

be construed in any way to waive or otherwise affect the ability of Baxter to challenge the reasonableness of Relator's purported expenses, attorneys' fees and costs.

F. This Settlement Agreement is neither an admission of liability by Baxter nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Baxter shall pay to the United States \$2,157,679.93 plus interest accrued thereon at a rate of 1.1 percent per annum from January 1, 2017, to the date of payment ("Settlement Amount") no later than fourteen days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Western District of North Carolina.

2. Conditioned upon the United States receiving the Settlement Amount from Baxter and as soon as feasible after receipt, the United States shall pay \$431,535.99 to Relator by electronic funds transfer pursuant to written instructions to be provided by counsel to Relator, Thomas L. Odum, Jr. and Anthony Scheer, to the United States Attorney's Office for the Western District of North Carolina.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Defendant's full payment of the Settlement Amount, the United States releases Baxter together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them from any civil

or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. 1320a-7a, or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Conditioned upon Baxter's full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases and forever discharges Baxter together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successor and assigns of any of them; agents; servants; employees; attorneys; representatives; partners; officers; directors and assigns from any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and from any and all claims, actions, damages, liabilities, losses, expenses, compensations, reimbursements, rights, suits, proceedings and causes of action of whatsoever kind or nature, in law or in equity that Relator asserted or could have asserted in the Civil Action. Relator expressly reserves and does not dismiss or release his claims against Baxter for attorneys' fees, expenses, and costs pursuant to 31 U.S.C § 3730(d).

5. Notwithstanding the release given in paragraphs 3 and 4 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal healthcare programs, or the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relators and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. §3730, and from any claims to a share of the proceeds of this Agreement and the Civil Action.

7. Baxter waives and shall not assert any defenses Defendant may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. Baxter fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Baxter has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution.

9. Baxter fully and finally releases the Relator from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Baxter has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof. Baxter expressly reserves any and all defenses it may raise to the reasonableness of any claims that Relator may assert under 31 U.S.C. § 3730(d) for expenses, attorneys' fees, and costs.

10. a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Baxter, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any criminal resolution of matters alleged in the Civil Action;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Baxter's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and the criminal resolution of matters resolved in the Civil Action;
- (5) the payment Baxter makes to the United States pursuant to this Agreement and any payments that Baxter may make to Relator, including costs and attorneys' fees,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Baxter, and Baxter shall not charge such Unallowable Costs directly or indirectly to any contract with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Baxter or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Baxter further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Baxter or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Baxter agrees that the United States, at a minimum, shall be entitled to recoup from Baxter any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected

agencies. The United States reserves its rights to disagree with any calculations submitted by Baxter or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Baxter or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Baxter's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 12 (waiver for beneficiaries paragraph), below.

12. Baxter agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

13. Upon receipt of the payment described in Paragraph 1, the United States and Relator shall promptly sign and file in the Civil Action a Stipulation of Dismissal with prejudice in the Civil Action as to the claims for the Covered Conduct.

14. Except as expressly provided to the contrary in this Agreement regarding Relator's claim of entitlement to Baxter's payment of Relator's reasonable expenses and reasonable attorney's fees and costs, and Baxter's right to challenge the reasonableness of any such claim, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

15. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

16. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Western District of North Carolina. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

17. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

18. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

19. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

20. This Agreement is binding on Baxter's successors, transferees, heirs, and assigns.

21. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

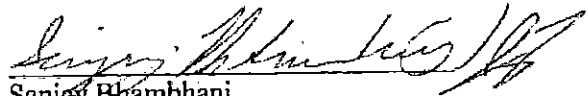
22. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

23. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

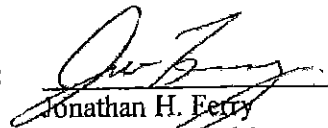
DATED: 1-11-17

BY:


Sanjay Bhambhani
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1-11-17

BY:


Jonathan H. Ferry
Assistant United States Attorney
United States Attorney's Office for the
Western District of North Carolina

BAXTER

DATED: IAN 03 2017

BY: _____

David P. Scharf
Corporate Vice President, General Counsel
Baxter Healthcare Corporation
Baxter International, Inc.

DATED: _____

BY: _____

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*Counsel for Baxter International, Inc., and
Baxter Healthcare Corporation*

BAXTER

DATED: _____

BY: _____

David P. Scharf
Corporate Vice President, General Counsel
Baxter Healthcare Corporation
Baxter International, Inc.

DATED: 1/3/17

BY: _____

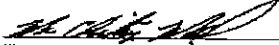
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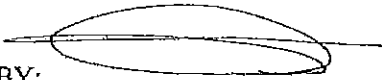
*Counsel for Baxter International, Inc., and
Baxter Healthcare Corporation*

WARREN CHRISTOPHER WALL


DATED: 1-4-17

BY: 
Warren Christopher Wall
Relator

DATED: 1-4-17

BY: 
Anthony Scheer
Counsel to Relator

DATED: 1/4/17

BY: 
Thomas L. Odom, Jr.
Counsel to Relator